National and International Quality Standards in the Pulmonary Function Laboratory

Carl Mottram, RRT RPFT FAARC
Director - Pulmonary Function Labs & Rehabilitation
Associate Professor of Medicine - Mayo Clinic College of Medicine
Case Presentation

- 31 y.o. female

- History of present illness
  - Non-specific cough, tightness in throat and episodic shortness of breath following URI
  - No wheezing noted by patient or on exam
  - Exam normal other than obesity (BMI 38)

- LMD orders CXR and spirometry with diffusing capacity
Case Presentation

- CXR
- Spirometry & DLCO

<table>
<thead>
<tr>
<th></th>
<th>Pre</th>
<th>Post</th>
<th>%Pred</th>
</tr>
</thead>
<tbody>
<tr>
<td>FVC</td>
<td>2.10</td>
<td>2.11</td>
<td>62%</td>
</tr>
<tr>
<td>FEV₁</td>
<td>0.89</td>
<td>1.36</td>
<td>31%</td>
</tr>
<tr>
<td>Ratio</td>
<td>42.4</td>
<td>64.5</td>
<td></td>
</tr>
<tr>
<td>DLCO</td>
<td>8.0</td>
<td></td>
<td>30%</td>
</tr>
</tbody>
</table>

Impression: Severe obstruction with a severe reduction in DLCO. Some improvement with BD
Case Presentation

- LMD Action Plan
  - Orders a CT scan
  - Referred to Mayo Clinic for further evaluation
Case Presentation

• Outside CT negative

• Pulmonary, ENT, and GI consults scheduled

• Pulmonary physician
  • Negative exam
  • Lungs clear, patient had coughing spell during exam, no wheezing or stridor noted
  • Questioned outside spirometry results and orders PFT’s
Case Presentation

- Spirometry & DLCO

<table>
<thead>
<tr>
<th></th>
<th>Pre</th>
<th>Post</th>
<th>%Pred</th>
</tr>
</thead>
<tbody>
<tr>
<td>FVC</td>
<td>2.55</td>
<td>2.48</td>
<td>75%</td>
</tr>
<tr>
<td>FEV1</td>
<td>2.27</td>
<td>2.25</td>
<td>79%</td>
</tr>
<tr>
<td>Ratio</td>
<td>89</td>
<td>90.7</td>
<td></td>
</tr>
<tr>
<td>DLCO</td>
<td>24.2</td>
<td></td>
<td>99%</td>
</tr>
</tbody>
</table>

Impression: Borderline restriction most likely due to obesity with no evidence of airflow obstruction or BD response.
PFT results affect people!!!
Evidence of Quality Testing

- **Spirometry in Primary Care Practice** *
  - 30 primary care clinics, 15 trained group / 15 usual group
  - 3.4% in usual group and 13.5% in trained group met ATS acceptability and reproducibility criteria
  - 1,012 pt. tests, 2,928 blows (2.89)
Evidence of Quality Testing

- Improving the Quality of Bedside Spirometry
  - Audit of testing outside the PF lab - Cleveland Clinic
  - 15% - ATS acceptability/reproducibility criteria
  - CI Project - 63.5% acceptability/reproducibility
  
Evidence of Quality Testing

Certification of DLCO Measurements for Clinical Trials

• Results of the initial DLco simulation tests from 125 pulmonary laboratories
  • 94 (75.2%) Passed with coaching; no hardware
  • 24 (19.2%) Failed. Passed after servicing
  • 6 (4.8%) Failed. Passed with new equipment
  • 1 (0.8%) Site dropped 1

• All DLCO simulations were completed by one individual from DAP using the same simulation device from May 2009 to March 2011.

• 24 instruments were tested at the 13 sites.

• 24 instruments, 17 (70.8%) met the target range and 7 (29.2%) were outside the 10% target range.

• Lack of routine instrument maintenance, medical gases, defective demand valve, defective electronic components, defective flow sensor, defective sample pump, defective carbon monoxide gas analyzer.

• Post intervention, all instruments met the expected target range.
• Diagnostic Accreditation Program (DAP) of British Columbia.

• 23 sites and 40 instruments

• Instruments represented four vendors and multiple software versions

<table>
<thead>
<tr>
<th>Biologic Quality Control Summary Data</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>Average</td>
</tr>
<tr>
<td>SD</td>
</tr>
<tr>
<td>CV</td>
</tr>
</tbody>
</table>
Evidence of Quality Testing

Results from a survey of PFT labs in Europe and Latin America

Enright, Blonshine, Harris 2007 ERS abstract
Guidelines and Standards

• American Thoracic Society
  • 1987 Revised Spirometry Standards
  • 1994 Revised Spirometry Standards
  • 1995 Diffusing Capacity
  • 1999 Guidelines for Methacholine and Exercise Challenge Testing
• ATS/ERS 2005 Series:
  • General Laboratory, Spirometry, Diffusing Capacity, Lung volumes, and Interpretation
• 2017 ERS/ATS Diffusion of the lung
Resources for Success

• American Thoracic Society
  • ATS Pulmonary Function Laboratory Management and Procedure Manual
    • 3rd Edition 2016
  • www.thoracic.org
  • Education
  • Education Products
Resources for Success

- Clinical and Laboratory Standards Institute “Quality Systems and Laboratory Practice Committee”
  - Professionals
  - Government – FDA, CDC, CMS
  - Industry
CLSI’s Quality Systems

- QMS01-A4: Quality Management Systems A Model for Laboratory Services
- QMS04-A2: Quality Systems in Respiratory Care

Patient assessment → Clinical interpretation → QSE → Path of workflow → Patient assessment

Path of workflow
Quality Systems in the PFL
Quality Assurance

CLSI’s “Path of workflow” Model
Quality Systems in the PFL

Pre-test

• Pre-test instructions
• Appropriate order
• Questionnaire
• Height* and weight
• Equipment quality assurance program
Quality Systems in the PFL Pre-test

• Subject preparation

• Activities that should preferably be avoided prior to lung function testing.
  • Smoking within 1 hours of testing
  • Consuming alcohol within 4 hours of testing
  • Performing vigorous exercise within 30 minutes of testing
  • Wearing clothing that substantially restricts full chest and abdominal expansion
  • Eating a large meal within 2 hours of testing

• Deviations recorded

2005 ATS/ERS Standards
General Laboratory
Quality Systems in the PFL Pre-test

- Height and weight
  - Measured in indoor clothes without shoes
  - Patients with deformities of the thoracic cage should have their arm span measured
- Regression equations
  - $Ht = \text{arm span}/1.06$

<table>
<thead>
<tr>
<th>Height Comparisons</th>
<th>PF Laboratory Height</th>
<th>HIM Height</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>182.7</td>
<td>184.5</td>
<td>-1.8</td>
<td></td>
</tr>
<tr>
<td>162.2</td>
<td>165.9</td>
<td>-3.7</td>
<td></td>
</tr>
<tr>
<td>171.7</td>
<td>175.8</td>
<td>-4.1</td>
<td></td>
</tr>
<tr>
<td>183.5</td>
<td>185.8</td>
<td>-2.3</td>
<td></td>
</tr>
<tr>
<td>190.6</td>
<td>190.1</td>
<td>0.5</td>
<td></td>
</tr>
<tr>
<td>171.5</td>
<td>173.7</td>
<td>-2.2</td>
<td></td>
</tr>
<tr>
<td>164.2</td>
<td>164.7</td>
<td>-0.5</td>
<td></td>
</tr>
<tr>
<td>169</td>
<td>175</td>
<td>-6</td>
<td></td>
</tr>
<tr>
<td>181.2</td>
<td>183.6</td>
<td>-2.4</td>
<td></td>
</tr>
<tr>
<td>159.8</td>
<td>165.1</td>
<td>-5.3</td>
<td></td>
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<td>162.6</td>
<td>181.6</td>
<td>1</td>
<td></td>
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<tr>
<td>185.7</td>
<td>186</td>
<td>-0.3</td>
<td></td>
</tr>
<tr>
<td>173.2</td>
<td>173.3</td>
<td>-0.1</td>
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<tr>
<td>168.4</td>
<td>168.4</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>168.5</td>
<td>171.3</td>
<td>-2.8</td>
<td></td>
</tr>
</tbody>
</table>

Min (cm) -6.00
Max (cm) 1.00

2005 ATS/ERS Standards
General Laboratory
Quality Systems in the PFL
Pre-test

- Equipment quality assurance
  - Validation/Verification
  - Preventive maintenance
  - Documentation and records (logbooks)

- Mechanical models
- Biological models
Quality Systems in the PFL

Pre-test

• Mechanical Model
  • 3-liter syringe – Daily and weekly
    • 0.5, 1-2, 6 second flows
  • Leak checked
  • Stored and used in such a way as to maintain the same temperature and humidity of the testing site
  • Validated based on manufacturer recommendations

2005 ATS/ERS Standards
Standardization of Spirometry
Quality Systems in the PFL
Pre-test

Mechanical Model - Plethysmography

- Validation using a known volume should be performed periodically

- Model lung with thermal mass to simulate isothermal conditions of the lung.

- Accuracy 50 ml or 3%

2005 ATS/ERS Standards
Standardization of Lung Volumes
Quality Systems in the PFL Pre-test

- Mechanical Model – Dilution techniques
- Analyzer accuracy and linearity
- N₂ washout: Monthly, exhalation volumes should be checked with the syringe filled with room air, and inhalation volumes with the syringe filled with 100% O₂.

2005 ATS/ERS Standards Standardization of Lung Volumes
Quality Systems in the PFL Pre-test

- Mechanical Models – DLCO
  - 2.5% volume acceptability range
  - Syringe DLCO weekly or whenever problems occur
  - $V_A, VC$ BTPS $\sim 3.2$ - $3.3L$

- DLCO Simulator or BioQC

2017 ERS/ATS Standardization of DLCO
Quality Systems in the PFL
Pre-test

• Biological Model
  • Normal laboratory subjects
  • Two individuals (16)
  • Establish mean and SD (minimum 20 samples)

2005 ATS/ERS Standards
General Laboratory
Quality Systems in the PFL
Pre-test

Biological Control – Lung volume

- At least monthly or whenever errors are suspect, 2 reference subjects (biologic controls) should be tested.
Quality Systems in the PFL Pre-test

Biologic Control – Diffusing Capacity

- At least weekly
- *Or* whenever errors are suspect
- *Or* whenever a calibration tank is replaced

![Graph of DLCO and VA from Diffusing Capacity BioQC Technologist #3]

2017 ERS/ATS - Standardization of DLCO
Quality Systems in the PFL
Biological Quality Control - PF Lab

• Results “Out of range”
  • Repeat with another technologist
  • Second tech is within limits - record out of range data

Biologic Quality Control Variability Among Pulmonary Function Testing Systems in a Large Academic Outpatient Pulmonary Function Laboratory

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>VC</th>
<th>FEV₁</th>
<th>TLC-Pleth</th>
<th>FRC-Pleth</th>
<th>sRaw</th>
<th>DLCO</th>
<th>VA</th>
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<tbody>
<tr>
<td>Average Sample Individual BioQC Across all 12 test systems</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>SD</td>
<td>140</td>
<td>0.10</td>
<td>0.05</td>
<td>0.08</td>
<td>0.21</td>
<td>1.18</td>
<td>0.76</td>
<td>0.21</td>
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<tr>
<td>CV</td>
<td></td>
<td>2.98</td>
<td>1.86</td>
<td>1.35</td>
<td>6.07</td>
<td>8.37</td>
<td>3.58</td>
<td>4.17</td>
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<tr>
<td>Average Twelve BioQC Subjects Across all 12 test systems</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>SD</td>
<td>130</td>
<td>0.11</td>
<td>0.07</td>
<td>0.11</td>
<td>0.19</td>
<td>0.53</td>
<td>1.07</td>
<td>0.19</td>
</tr>
<tr>
<td>CV</td>
<td></td>
<td>3.24</td>
<td>2.57</td>
<td>1.97</td>
<td>6.39</td>
<td>11.19</td>
<td>5.03</td>
<td>3.82</td>
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</table>

Mottram
ERS 2013
Abstract
Abnormal Study: Mild airway obstruction with a significant response to bronchodilator. Lung volumes suggest hyperinflation. DLCO is within normal limits.
“In my experience, it's easier to correct a QC failure on an ABG analyzer than on PFT equipment. The conflict in my experience has been with justifying the closure of a PFT lab because of a QC issue that I have difficulty resolving,...”

“I've had weeks of headaches with DLCO results that were questioned by a physician, and did seem to be a bit high, but which were not resolved although flow sensors, analyzers, and circuits and tubings were replaced. What caused the problem?”

“I have yet to find someone with stable values plus we are so busy it is almost impossible to schedule staff to do these studies.”

“We need a subject to be the National Human PFT Biocontrol, who will travel the country subjecting himself/herself to testing so the results can be compared to the National Reference Lab (Mayo ??).”
National BioQC Subject!
“This is fine as far as it goes. From here on, it’s who you know.”
Quality Systems in the PFL Test

- Testing room environment
  - Environmental interference
- Technologist’s performance & training - QSE: Personnel
  - Second technologist
- Meeting ATS/ERS acceptability and repeatability criteria
Quality Systems in the PFL

Test - QSE: Personnel

- Technologists
  - Job qualifications
  - Job descriptions
  - Orientation
  - Training
  - Competency assessment
  - Continuing education
  - Performance appraisal
Quality Systems in the PFL
Test - QSE: Personnel

- Competence Assessment
- Training and on-going performance evaluations
- NIOSH Spirometry Training Course
  - cdc.gov/NIOSH/topics/spirometry
- AARC’s Spirometry Training
- National Board for Respiratory Care
  - PFT exams
Quality Systems in the PFL Test - QSE: Personnel

Harmonising spirometry education with HERMES: training a new generation of qualified spirometry practitioners across Europe

I. Steenbruggen*, S. Mitchell®, T. Severin®, P. Palange1 and B.G. Cooper1 on behalf of the Spirometry HERMES Task Force

- Harmonizing Education in Respiratory Medicine for European Specialists

Eur Respir J 2011; 37: 479–481
Quality Systems in the PFL Test - Reference equations

• NHANES III
  - Spirometry only
  - ATS/ERS recommended
  - ERS GLI Taskforce “All-Age Approach”

• Diffusing capacity
  - Many choices, none recommended

• Lung volumes - limited
http://www.lungfunction.org/

ERS Task Force founded in 2008
Multi-ethnic reference values for spirometry for the 3–95-yr age range: the global lung function 2012 equations

Eur Respir J 2012; 40: 1324–1343
“All-Age Approach”
Multi-ethnic reference values for spirometry for the assessment of lung function

- 160,000 data points from 72 centers in 33 countries
- 97,759 records of healthy nonsmokers (55.3% females) aged 2.5–95 yrs.
- Reference equations were derived for healthy individuals aged 3–95 yrs for Caucasians (n=57,395), African–Americans (n=3,545), and North (n=4,992) and South East Asians (n=8,255).

**TABLE 1** Summary of datasets included in the initial analysis

<table>
<thead>
<tr>
<th>Group</th>
<th>Countries</th>
<th>Males</th>
<th>Females</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>N</td>
<td>Age range yrs</td>
</tr>
<tr>
<td>African–American</td>
<td>1</td>
<td>1529</td>
<td>6–85</td>
</tr>
<tr>
<td>India and Pakistan</td>
<td>2</td>
<td>2837</td>
<td>4–86</td>
</tr>
<tr>
<td>Latin America</td>
<td>5</td>
<td>2337</td>
<td>6.7–89.4</td>
</tr>
<tr>
<td>Mexican–American</td>
<td>1</td>
<td>1622</td>
<td>6.2–86</td>
</tr>
<tr>
<td>Iran</td>
<td>1</td>
<td>3398</td>
<td>5–85</td>
</tr>
<tr>
<td>Oman</td>
<td>1</td>
<td>638</td>
<td>6–65</td>
</tr>
<tr>
<td>North East Asia</td>
<td>2</td>
<td>2176</td>
<td>15.3–91</td>
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<tr>
<td>South East Asia</td>
<td>4</td>
<td>4187</td>
<td>3.3–88</td>
</tr>
<tr>
<td>North Africa</td>
<td>2</td>
<td>541</td>
<td>6–78</td>
</tr>
<tr>
<td>Caucasian</td>
<td>14</td>
<td>24229</td>
<td>2.5–95</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>199</td>
<td>6.2–93</td>
</tr>
<tr>
<td>Total</td>
<td>33</td>
<td>43693</td>
<td>2.5–95</td>
</tr>
</tbody>
</table>

*: total sample included 97,759 subjects.
Quality Systems in the PFL Post-Test

- Maneuver selection
- Quality review by second technologist
- “While in-house training may achieve the desired goals, laboratory directors should strongly consider the benefits of formal training programs from outside providers.”
- Feedback to the technicians concerning their performance should be provided on a routine basis

2005 ATS/ERS Standards
General Laboratory
Quality Systems in the PFL Post-Test

• Consistent Interpretation (ATS/ERS Guideline)

• Turn-around time
  • Average TRT: <1 day (15%), 1-2 d (30%), 3-4 d (27%), 5-6 d (15%), >7 d (3%)
  • ATS PFL Registry Abstract AARC 2005, OF-05-037
  • Mayo’s PFL: ½ day to Electronic Medical Record
Quality Systems in the PFL Does it Work?

- Retrospective review of 18,000 consecutive pts. at Mayo Clinic
- Ninety percent of the patients were able to repeat FEV1 within 120 ml (6.1%), FVC within 150 ml (5.3%), and PEF within 0.80 L (12%).

Repeatability of Spirometry in 18,000 Adult Patients

Paul L. Enright, Kenneth C. Beck, and Duane L. Sherrill

Accreditation Models
How many have had JCAHO come into your lab and actually perform an inspection?
• Self-assessment questionnaire
• Submission of the application forms, along with the laboratory procedure and policy manuals
• Site visit by the accreditation assessment panel
• Submission of BioQC and mechanical model data for review/feedback

• Checklist for self and on-site inspections based on the ATS-ERS recommendations
US Based Pulmonary Function Laboratory Accreditation

- **American Thoracic Society**

- Appointed an Expert Panel to discuss accreditation model.

### ATS Pulmonary Function Laboratory Accreditation Program

**Planning Committee Members:**

- David Kaminsky, MD, University of Vermont
- Allan Coates, MD, Hospital for Sick Children, Toronto, Canada
- Patricia Clark, RPFT, University of Washington
- Bruce Culver, MD, University of Washington
- Allen Dozor, MD, New York Medical College
- Paul Enrigh, MD, University of Arizona
- **Carl Mottram, RRT, RPFT, FAARC, Mayo Clinic**
- Timothy Myers, MBA, RRT, FAARC
- Margaret Rosenfeld, MD, Children’s Hospital Regional Med. Ctr, Univ. of Washington
- Gregg Ruppel, MEd, RRT, RPFT, FAARC, St. Louis University
- Daniel Weiner, MD, Children’s Hospital of Pittsburgh

- Steven Crane, MD, ATS
- Barbara Horner, ATS
Accreditation in PF Labs

• Integrate new QA recommendations into your lab practice now!

• Questions??